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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,622	03/30/2005	John D. Cleary	11636N/020724	1994
32885	7590	09/19/2006	EXAMINER PESELEV, ELLI	
STITES & HARBISON PLLC 424 CHURCH STREET SUITE 1800 NASHVILLE, TN 37219-2376			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/529,622	CLEARY ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lopez-Berestein et al (U.S. Patent No. 4,663,167).

Lopez-Berestein et al disclose a method of treating fungal infections with a composition comprising amphotericin B. The claimed methods and compositions are anticipated by Lopez-Berestein et al. In addition, if there is a difference in purity of

amphotecin B disclosed by Lopez-Berestein et al and amphotericin B encompassed by the present claims, such difference is seen to be minor in nature and the claimed methods and compositions , which fall within the scope of the prior art's method and composition, would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made.

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berenstein et al (U.S. Patent No. 4,663,167) in view of Michel et al (U.S. Patent No. 4,902,789) or Tang (U.S. Patent No. 4,308,375).

Lopez-Berestein et al disclose a method of treating fungal infections with a composition comprising amphotericin B but do not disclose purification of amphotericin B. However, since purification of amphotericin B was well known in the art at the time the claimed invention was made as disclosed by Michel et al or Tang, a person having ordinary skill in the art at the time the present invention was made to use purified amphotericin B in the composition and method disclosed by Lopez-Berestein et al because such a person would have expected less side effects with administration of purified amphotericin B.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berestein et al (U.S. Patent 4,663,167) in view of Michel et al (U.S. Patent No. 4,902,789) or Tang (U.S. Patent No. 4,308,375) as applied to claims 1-10 and 12-16 above, and further in view of Ono et al (U.S. Patent No. 4,656,288).

Each of Michel et al and Tang discloses purification of amphotericin B but does not disclose purification of amphotericin B using high pressure liquid chromatography

fractionation. However, since purification of antibiotics using high pressure liquid chromatography fractionation was well known in the art at the time the present invention was made as disclosed by Ono et al (column 9, lines 58-64), a person having ordinary skill in the art at the time the present invention was made would have been motivated to purify amphotericin B using a conventional method disclosed by Ono et al because such a person would have expected that the resulting amphotericin B will have a high degree of purity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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